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510(k) Summary

Date Prepared: February 26, 2001

1. **Sponsor**

A. Sponsor Name

Vitrolife AB
(subsidiary Xvivo Transplantation Systems AB)
Mölndalsvagen 30, SE-412 63, Gothenburg, Sweden
Tel: 46 31 721 8060 Fax: 46 31 721 80 99

Contact Name: Mr. Eiler Anderson
QA & RA Director

B. Submission Correspondent

Karl Posselt
FDA Regulatory Services
155 Cider Mill Road
Ringoes, NJ 08551
Tel: (908) 284-2246 Fax: (908) 284-2246
E-mail: posselt@blast.net

2. **System Identification**

A. Proprietary Name

Perfadex® Solution for Lung Perfusion

B. Common or Usual Product Name

Solution for Organ Perfusion

C. Product Classification

Class II Panel No. 78 KDL

3. Predicate Device

A. Name

Classification Name: Set, Perfusion, Kidney, Disposable
Regulation Number: 876.5880
510 (k) No. K 884609
Euro-Collins Solution Sets
Fresenius USA, Inc.

B. Indications for Use

The solution is indicated for the flushing of isolated kidneys after removal from the donor in preparation for the storage, transportation and eventual transplantation into a recipient.

C. Device Description

Euro-Collins (electrolyte solution for kidney preservation) is a clear, sterile, non-pyrogenic solution used for flushing and storage of isolated kidneys. This solution has an approximate calculated osmolarity of 375 mOsm/L, a sodium concentration 10 mmol/L, a potassium concentration of 115 mmol/L, and a pH of approximately 7.2 at 4°C. The composition of Euro-Collins is thus consistent with that of an intracellular fluid.

4. Perfadex® Device Information

A. Indications for Use

Perfadex® is indicated for the flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

B. Device Description

Perfadex® is a clear, sterile, non-pyrogenic, extracellular type solution for hypothermic flushing and storage of isolated lungs. The solution is slightly acidic (pH 5.5) to permit long shelf life and is adjusted shortly before use to pH 7.4. The solution is slightly hypertonic (osmolarity 295 mOsm/L) and has a low buffering capacity. The composition of Perfadex® is thus consistent with that of an extracellular solution.

Perfadex® is filled into 1 or 2.8 liter PVC (Viaflex) bags, each of which is sealed in an outer polypropylene bag and sterilized by autoclaving.

Manufacturing, control and sterilization is performed at an FDA inspected plant owned and operated by Fresenius Kabi in Halden, Norway. The product is stored at room temperature and has a shelf life of 3 years.

5. Substantial Equivalence

A. Indications for Use

Euro-Collins and Perfadex® have the same intended use. Both solutions are intended for flushing and cold storage of an isolated organ at the time of its removal from a donor in preparation for storage, transportation and eventual transplantation into a recipient.

B. Technological Characteristics

Euro-Collins and Perfadex® are clear, sterile, non-pyrogenic solutions. Perfadex® is essentially an "extracellular" type (low potassium, high sodium) solution whereas Euro-Collins is an "intracellular" type (high potassium, low sodium) solution.

Both solutions employ phosphates as buffers although the total phosphate content of Euro-Collins is much higher (57.5 mmol/L in Euro-Collins vs 0.8 mmol/L in Perfadex®. While both solutions contain glucose, the glucose content of Euro-Collins is much higher (ca 3.5%) than that of Perfadex® (ca 0.1%). Unlike Euro-Collins Perfadex® contains a polysaccharide, dextran 40 USP (5%) which makes the solution slightly hyper-colloid osmotic compared with plasma.

C. Performance Data

Retrospective comparative data was obtained from 3 study centers where Perfadex® and Euro-Collins solutions were used to preserve lungs for human transplantation.

Perfadex® was used in 91 patients and Euro-Collins in 112 patients. Complete data which is available from the three centers indicates that the use of Perfadex® in pulmonary transplantation leads to improved immediate graft function, a reduction in the need for post-transplant ventilatory support and equivalent short and long term survival.

Both groups were comparable in terms of age, gender and the primary indications for transplant.

In these studies the number of patients surviving 7 days post transplant, the number of patients successfully extubated within 48 hours post transplant and the number of patients surviving 30 days post transplant were comparable in both the Perfadex® and Euro-Collins groups. The time (days/hours) on ventilatory support post transplant was considerably shorter in the Perfadex® group.

Although Perfadex® patients were exposed to longer periods of ischemia and the length of surgery was longer in these patients the survival rate, the duration of ventilation therapy and the length of ICU stay was shorter compared to that for Euro-Collins patients. Post operative lung function as assessed by PaO2/FiO2 or $AaDO_2$ was better in the Perfadex® patients as compared to the Euro-Collins patients. The incidence of severe graft dysfunction was higher in the Euro-Collins group (18%) than in the Perfadex® group (10%). Thirty (30) day mortality was 9.8% in the Euro-Collins group and 5.5% in the Perfadex® group.

Substantial equivalence was also demonstrated for overall adverse events and pulmonary related serious adverse events.

Pre-clinical studies conducted on rodents, rabbits, dogs, pigs, and primates (baboons) demonstrate that Perfadex® treated lungs performed statistically better than those preserved in Euro-Collins.

Other pre-clinical studies demonstrate the non-toxicity and biocompatibility of Perfadex® (all components are of compendial, USP, Ph.Eur. or BP quality) and the product's sterility and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

Vitrolife AB
c/o Mr. Karl A. Posselt
Regulatory Services
155 Cider Mill Road
RINGOES NJ 08551

Re: K000881
Perfadex® Solution for Lung Preservation
Dated: January 11, 2001
Received: January 12, 2001
Regulatory Class: II
21 CFR §876.5880/Procode: 78 MSB

Dear Mr. Posselt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Statement Of Indications For Use

STATEMENT OF INDICATIONS FOR USE

Perfadex® Solution for Lung Perfusion is indicated for the flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000881